PRIMARY CARE TRUST SENIOR PHARMACIST v PFIZER

Promotion of Champix

A senior pharmacist to a primary care trust complained that a presentation on Champix (varenicline) given by a Pfizer representative to the local stop smoking service constituted advance notification as the product was not yet launched. In that regard the complainant noted that the smoking cessation service did not make policy decisions about the entry of new medicines into the local health community nor did it hold budgetary responsibility for such decisions.

The Panel noted that when the presentation was made to the smoking cessation service, Champix had a marketing authorization, albeit that Pfizer had chosen to delay its formal launch. Thus there could be no breach of the Code as alleged and the Panel ruled accordingly.

The senior pharmacist to a primary care trust (PCT) prescribing and management team complained about a presentation on Champix (varenicline) given by a representative of Pfizer Limited to members of the stop smoking service.

COMPLAINT

According to an email from the representative the aim of the presentation was to model the financial and clinical impact of introducing Champix within a defined health economy. Pfizer anticipated a formal launch for Champix in December 2006. The stop smoking service had indicated its wish for Champix to be considered for approval for use within the area. The email sought an appointment with the complainant so that he could have a similar presentation to that already made and it also invited him to a more detailed clinical presentation by the regional medical research specialist.

The complainant stated that the smoking cessation service did not make policy decisions about the entry of new medicines into the local health community nor held budgetary responsibility for such decisions. In this context the complainant was concerned that this activity constituted advance notification which was not allowed under Clause 3.1 of the Code.

When writing to Pfizer, the Authority asked it to respond in relation to Clauses 2, 3.1 and 9.1 of the Code.

RESPONSE

Pfizer stated that the European Medicines Evaluation Agency (EMEA) issued a marketing authorization for Champix on 26 September 2006. The regulatory status of Champix was explained at the meeting and attendees were told that, although Champix had received its marketing authorization, Pfizer would not be generating demand or promoting it until after a formal launch.

Pfizer explained that the presentation to the stop smoking service was given in response to an unsolicited request from the service for information on Champix, apparently following requests for information from local general practitioners. The representative who was asked, correctly referred the enquiry to a member of the primary care account management (PCAM) team, who were, amongst their other responsibilities, responsible for informing budget holders about new products prior to launch. The PCAM concerned arranged the meeting and confirmed beforehand that those planning to attend were, as stated by the representative, budget holders for smoking cessation products. Prior to starting the meeting, the PCAM gained confirmation from those present that they were indeed budget holders for smoking cessation products. A list of those present at the meeting was provided.

The PCAM presented the local budget impact model for Champix. A copy of the model with the calculated outcome was provided to the Authority. The PCAM also left a copy of the Champix pre-launch formulary summary for English PCTs and a smoking cessation backgrounder for the head of service, copies of which were also provided.

The complainant suggested that this was advance notification, which was not, in these circumstances in breach of the Code. Champix was licensed at the time of the meeting and so there had been no breach of Clause 3.1.

Pfizer believed that the referral and the presentation and all the materials were appropriate and that Pfizer personnel had acted correctly. Pfizer believed that it was appropriate to make this presentation to these recipients for the reasons stated above.

Therefore Pfizer did not consider that this activity constituted a breach of Clause 9.1 or of Clause 2.

PANEL RULING

The Panel noted that the supplementary information to Clause 3.1 set out the basis upon which information about medicines which were not the subject of

marketing authorizations could be given. At the time that the presentation was made to the smoking cessation service in question, however, Champix had a marketing authorization, albeit that Pfizer had chosen to delay its formal launch. Thus there could be no breach of Clause 3.1 as alleged and the Panel ruled accordingly. It followed that there was also no breach of Clauses 9.1 and 2.

Complaint received **10 November 2006**

Case completed **29 January 2007**